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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10 072,539	02/08/2002	Kevin B. Morton	NEOMTRX-4C1DV3	3961

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EXAMINER

DAVIS, RUTH A

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 01/27/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/072,539

Applicant(s)

MORTON ET AL.

Examiner

Ruth A. Davis

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Objections

1. Claim 16 is objected to because of the following informalities: the term "pivotably" should be spelled correctly "pivotally". Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1 – 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and its dependents are drawn to a method for obtaining intraductal fluid, however are rendered vague and indefinite because the claim fails to recite essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a step for collecting or obtaining the intraductal fluid. Applicant may prefer to include "whereby a sample of intraductal fluid is obtained" at the end of the claim to more clearly define the invention.

In claim 10, lines 1 – 2, "the heated fluid" lacks sufficient antecedent basis.

In claim 15, line 2, "the inflation cycle" lacks sufficient antecedent basis.

Claims 10, 12, 13 and 15 are confusing because it is unclear if the dependency is intended as recited. For example, claim 10 appears to rather depend from claim 9, claim 12 appear to rather depend from claim 1 or 11, and claim 15 appears to rather depend from claim 11.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1 – 4, 6 – 8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Love et al. (US 6494859).

Applicant claims a method for obtaining a sample of intraductal fluid, the method comprising providing an intraductal fluid sampling device having an adjustable support, at least

one inflatable bladder carried by the support and a patient interface surface carried by the bladder; adjusting the support to fit a breast to be tested; contacting the interface with the breast; and inflating the bladder to compress the breast. The adjusting step occurs before the contacting step, or alternatively, the contacting step occurs before the adjusting step. The adjusting step comprises adjusting the support to fit the breast without compression; the contacting step comprises contacting the interface surface with the breast such that at least a portion of the bladder may impart compression to the lactiferous sinus; the inflating step comprises compressing the lactiferous sinus or alternatively compressing the breast at least partially on the anatomically proximal aspect (of) to the lactiferous sinus. Finally the inflating step comprises inflating the bladder in cycles lasting about 1 – 30 seconds.

Love teaches method for obtaining intraductal fluid (abstract) comprising applying external pressure to the breast and collecting fluid (col.4 line 31-36). Love teaches that the pressure may be applied manually or mechanically (col.4 line 38-39) periodically, continuously or cyclically (col.4 line 45-47). Specifically, the pressure may be applied by a device designed to squeeze the breast, for example one with rollers, inflatable bladders, or other effective mechanisms for applying external pressure to the breast (col.8 line 23-29).

Love does not teach the method comprising the claimed sampling device. However Love does teach using a device wherein external pressure is applied for collection, such as one with an inflatable bladder. At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Love to use a device with an inflatable bladder with a reasonable expectation for successfully obtaining intraductal breast fluid. Although Love does not teach the adjusting, contacting and inflating steps as claimed, at the time of the claimed invention, it would


have been well within the purview of one of ordinary skill in the art to perfect adjustments, contacting steps and inflating steps as a matter of routine experimentation. In support Love teaches the pressure is applied cyclically (col.4 line 45-47) to various lactiferous ducts (examples, especially 4). Moreover, at the time of the claimed invention one of ordinary skill in the art would have been motivated by Love to apply a sampling device with an inflatable bladder to a breast with a reasonable expectation for successfully obtaining intraductal fluid.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-0196. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad
January 24, 2003


LEON B. LANKFORD, JR
PRIMARY EXAMINER